

(v) Look through the sight gage opening while using a flashlight pointed into the filler vent hole to verify the gears are meshed properly. Gears are properly meshed when the "X" marked on the pinion gear of the output cartridge is between the two "X's" marked on the gear of the input cartridge (see figure 3). Do not torque the MS20074-04-06 bolts until both cartridges are installed on the case and the gears are properly meshed. Torque the output cartridge bolts to 60 in.-lbs. first, then torque the input cartridge bolts to 60 in.-lbs. Safety wire with 0.032-inch stainless steel safety wire.

(vi) Reinstall sight gage with MS35769-11 or AN900-10 gasket. Oil threads to prevent threads from locking up. Torque to 200 in.-lbs.

(vii) Reinstall the chip detector with a MS35769-8 or AN900-9 gasket after lubricating the threads with oil. Torque the chip detector to 150 in.-lbs. Safety wire the sight gage to the chip detector using 0.032-inch stainless steel safety wire.

(viii) Fill the T/R gearbox with oil to the level indicated on the T/R sight glass decal. Reinstall the filler vent plug, P/N A610-1, with a MS35769-9 or AN900-8 gasket, after lubricating the threads with oil.

(ix) Inspect the T/R gearbox assembly to ensure that the shafts and gears rotate freely.

(7) Reinstall the T/R gearbox onto the helicopter in accordance with the applicable maintenance manual. Verify that the oil level of the T/R gearbox is at the recommended mark on the sight glass.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used when approved by the Manager, Los Angeles Aircraft Certification Office, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(f) This amendment becomes effective on December 27, 1995.

Issued in Fort Worth, Texas, on November 2, 1995.

Eric Bries,

Acting Manager, Rotorcraft Directorate,
Aircraft Certification Service.

[FR Doc. 95-28537 Filed 11-21-95; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name for three new animal drug applications (NADA's) from Vet-A-Mix, Inc., to Lloyd, Inc.

EFFECTIVE DATE: November 22, 1995.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1646.

SUPPLEMENTARY INFORMATION: Vet-A-Mix, Inc., 604 West Thomas Ave., P.O. Box A, Shenandoah, IA 51601, has informed FDA of a change of sponsor name for approved NADA's 92-836 (diethylcarbamazine citrate), 140-866 (yohimbine hydrochloride injectable), and 140-921 (prednisolone tablets) to Lloyd, Inc., 604 West Thomas Ave., Shenandoah, IA 51601. Accordingly, FDA is amending the regulations in 21 CFR 520.622c, 520.1880, and 522.2670 to reflect the change of sponsor name.

List of Subjects in 21 CFR Parts 520 and 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 522 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.622c [Amended]

2. Section 520.622c *Diethylcarbamazine citrate chewable tablets* is amended in paragraph (b)(3) by removing "011789" and adding in its place "061690".

§ 520.1880 [Amended]

3. Section 520.1880 *Prednisolone tablets* is amended in paragraph (b) by

removing "011789" and adding in its place "061690".

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

4. The authority citation of 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.2670 [Amended]

5. Section 522.2670 *Yohimbine injectable* is amended in paragraph (b) by removing "032998" and adding in its place "061690".

Dated: November 13, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95-28542 Filed 11-21-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Selenium/Vitamin E Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Fort Dodge Laboratories. The ANADA provides for subcutaneous or intramuscular use of a selenium/vitamin E injection for prevention and treatment of selenium/tocopherol deficiency syndrome in weanling calves and breeding beef cattle.

EFFECTIVE DATE: November 22, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Fort Dodge Laboratories, 800 Fifth St. NW., P.O. Box 518, Fort Dodge, IA 50501, filed ANADA 200-109, which provides for subcutaneous or intramuscular use of Velenium™ (selenium, vitamin E) Injection for prevention and treatment of selenium/tocopherol deficiency syndrome in weanling calves and breeding beef cattle. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of ANADA 200-109 for Fort Dodge's selenium/vitamin E injection is as a generic copy of Schering-Plough's Mu-Se® (selenium/vitamin E) Injection

in NADA 30-314. The ANADA is approved as of October 20, 1995, and the regulations are amended in 21 CFR 522.2100(d)(2) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.2100 is amended by revising paragraph (d)(2) to read as follows:

§ 522.2100 Selenium, vitamin E injection.

* * * * *

(d) * * *

(2) *Sponsors.* See Nos. 000061 and 000856 in § 510.600(c) of this chapter.

* * * * *

Dated: November 13, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95-28543 Filed 11-21-95; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Sarafloxacin Hydrochloride

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Abbott Laboratories. The NADA provides for use of sarafloxacin hydrochloride solution for injection in day-old broiler chickens for control of early mortality associated with *Escherichia coli* organisms susceptible to sarafloxacin.

EFFECTIVE DATE: November 22, 1995.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center For Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1644.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, 1401 Sheridan Rd., North Chicago, IL 60064-4000, filed NADA 141-018, which provides for use of SaraFlox® Injection (sarafloxacin hydrochloride solution for injection) to be used in day-old broiler chickens for control of early mortality associated with *E. coli* organisms susceptible to sarafloxacin. The NADA is approved as of October 12, 1995, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.2095 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning October 12, 1995, because the NADA contains reports of new clinical or field investigations and new human food safety studies essential to the approval and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental effects of

this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.2095 is added to read as follows:

§ 522.2095 Sarafloxacin solution for injection.

(a) *Specifications.* Each milliliter contains sarafloxacin hydrochloride equivalent to 50 milligrams of sarafloxacin in a 20 percent propylene glycol solution.

(b) *Sponsor.* See No. 000074 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.594 of this chapter.

(d) *Conditions of use.* Day-old broiler chickens:

(1) *Amount.* 0.1 milligram sarafloxacin per 0.2 milliliter dose.

(2) *Indications for use.* For control of early mortality in day-old broiler chickens associated with *Escherichia coli* organisms susceptible to sarafloxacin.

(3) *Limitations.* A single subcutaneous 0.2 milliliter injection in the neck. Dilute 1 milliliter of SaraFlox® with 100 milliliters of sterile water or physiologic saline to provide 0.1 milligram sarafloxacin in a 0.2 milliliter dose. Use entire contents of diluted solution within 24 hours. No preslaughter drug withdrawal period is required when the product is used as directed. Use in a manner other than that indicated or with dosages in excess of that recommended may result in illegal drug residues in edible tissues. Do not use in laying hens producing eggs for human consumption. Do not use in replacement layers or fowl intended for breeding